Patent Application of

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for

RES-Q-SCOPE

Field of the Invention

The present invention generally relates to an instrument for accessing the laryngeal area of the human body and, more particularly, to an improved portable miniaturized laryngoscope to use in the respiratory emergency field, pre-hospital emergency care and hospital setting for safe, indirect, visual endotracheal intubation.

Background Of the Invention

Laryngoscopes are widely known and used in the medical field to facilitate endotracheal intubation of a patient during a respiratory emergency situation in order to provide airway patency and positive air pressure through the upper airway and the lungs, manually or through mechanical ventilation of the lungs to the injured person. Such laryngoscopes are also used during surgical procedures to maintain an open airway and provide ventilatory support during surgery under anesthesia. In the human anatomy, the epiglottis normally overlies the glottis opening into the larynx to prevent the passage of food into the trachea during eating. Thus, when undertaking an endotracheal intubation, it is necessary to displace the epiglottis from the glottal opening to permit the air tube to be inserted in between the vocal cords and subsequently into the trachea.

Various laryngoscope constructions are known. The more widely used laryngoscopes consist of an elongate, rigid metal blade which is supportably attached to a handle. These types of laryngoscopes are inserted through the mouth of the patient into the pharyngeal area to

displace the tongue and epiglottis forcibly in the upwards direction and most often permitting direct visualization of the glottis through the mouth opening. The traditional laryngoscopes commonly have a light source which is directed along the blade to attempt to illuminate the area beyond the end of the blade. Since the mouth and laryngeal area are at an approximate 90 degrees to each other, such laryngoscopes require that the patient's head and neck be hyper extended in the backwards direction to create a relatively straight path to permit direct visualization of the glottis by the operator of the laryngoscope. Substantial force by the operator is required to overcome the natural skeleto-musculature tendencies of the patient and the operator is required to perform the procedure while located at the head of the patient. Additionally, if there is concern that the patient may have suffered spinal neck injuries; the technique for possible direct visualization of the glottis involves risk due to the potential for increased spinal and neck injury from this procedure. The common methods use conventional blades of the straight or curved type. The blade is inserted through the mouth into the throat passageway to forcibly displace the tongue and epiglottis and possibly expose the patient's glottis. The larynx may be viewed through the mouth opening from an observation position just above and behind the head of the patient by sighting generally along the axis of the blade. The endotracheal tube is inserted, either orally or trans-nasally, and passed alongside the blade and finally, through the glottis. The procedure is often more difficult by the presence of bodily fluids on or in the larynx and trachea which significantly reduces the visibility when using the common methods. Without visualization of anatomical structure, intubation of a patient during an emergency situation may require blind placement of an endotracheal tube based on free hand trial and error. Without proper positioning and guidance, the tubular members often cause trauma or injury to anatomical tissue, or missed intubation into the esophagus with potential fatal consequences.

Surgical instruments having means for indirect illumination and visualization of the pharyngeal areas of the body are known. U.S. Pats. Nos. 3,776,222 and 3,913,568 disclose devices for endotracheal intubation which comprise flexible or articulatable tubular probes generally, having internal fiber optics for lighting and viewing the internal areas of the body. As disclosed in those patents, the probes carry a slidably removable endotracheal tube surrounding their outer surfaces and the probe is directly inserted into the trachea to position the tube. Such devices obviously require the use of relatively large diameter endotracheal tubes in order to be carried on the tubular probe, and their use necessarily is limited to patients with sufficiently large airway passages to accommodate the combined size of the probe and endotracheal tube. Additionally, due to the flexible nature of the probes, it is difficult to manipulate the probe to displace the tongue and epiglottis to permit guidance during insertion of the tube into the trachea. These instruments require a high degree of skill and a concomitant degree of training to perform the procedure quickly, without injuring the patient. Additionally, because of expense, lack of portability, and sterilization requirements to prevent cross contamination among patients, these instruments are generally not available in a non-hospital setting.

As a consequence, there has been a long felt need for a device which can facilitate intubation so as to quickly and accurately accomplish indirect visual endotracheal intubation by manipulation of soft tissue in the mouth without forcefully needing to overcome the natural skeleto-musculature tendencies of the patient. There is a further need to for such a device which provides indirect visualization of the surrounding anatomical structures from a diversity of orientations relative to the patient being intubated. The safety and efficacy of procedures for introducing tubular members in the body can be greatly enhanced with the use of remote visualization and ability to visually verify and document the procedure in film or print. There is a further need also for such a device which is

disposable and inexpensive enough to be financially accessible for any emergency vehicle or field use, and which is easily and efficiently used by a practitioner with basic training, particularly for patients having a short, obese neck with a commonly anteriorly located upper airway. The need exists for an intubating device which provides clear and external digital imagery of upper laryngeal structures for ease of viewing by the practitioner by means of electronic screens or LCD displays. There is a further need for such a device which can effectively accommodate different diameters of intubation tubes, according to the individual patient's needs. There is a further need for such a device which can transport a pre-loaded endotracheal tube and place it at a ready position for final insertion from a short distance from the target organs, the vocal cords. There is the need for an intubation device which clusters the essentials for endotracheal intubation in a small an anatomically and user friendly device. Meaning, an endotracheal tube in a ready position with bend pressure ensuring a predictable exit direction, a clear day light illumination such as LED (Light Emitting Diode), suction capability at the working site, predetermined curvature to strategically locate at a close proximity to the target organs and a image carrying method such as a CMOS (Complementary Metal Oxide Semiconductor) digital system that brings the image to a hinge/ swivel multi positional LCD (Liquid Crystal Display) screen with minimal if any force required to perform the procedure with all the elements gently brought to the target area. There is the need for a fully miniaturized and hand held video intubation device, self contained and powered, which can be used in the field where the emergencies occur. Lastly, there is a further need for an intubating device which is partially or fully disposable with minimal potential cross contamination between patients due to poor cleaning of conventional equipment during multiple respiratory emergencies necessitating multiple, simultaneous and/or rapidly sequential intubations, such as in mass casualties scenarios.

Summary of the Invention

The present invention is designed to overcome the aforementioned difficulties during intubation in the medical emergency field by providing a disposable, inexpensive, minimal force, easily used and efficient endotracheal intubation device, designed for ready manipulation of oral cavity soft tissue during intubation avoiding traditional forceful intubation minimizing the effort and trauma of both patient and operator, by clustering the essential elements necessary for endotracheal intubations and bring them to a short distance from the target organs with minimal effort . A bright day light LED source and indirect visualization system composed of a digital or analog imaging system, coupled with a simultaneous suctioning ability, and external hinge/ swivel viewing LCD screen mechanism which can be placed at a multiplicity of positions and angulations relative to the patient, enabling an operator to visualize the anatomical structures located distally, visualize record the actual intubation process from a variety of locations around the patient.

In one preferred embodiment which comprises two electrically connecting pieces. A first end comprising a power housing assembly with a proximal extension by means of a hinge/swivel mechanism and a miniature LCD screen pivotally attached to the power source. The multiple positional LCD screen enables a variety of positions and angulations for viewing the endotracheal intubation procedure taking place distally. The power housing serves as handle and contains a power supply port, video output port, on/off switch and a distal end electrical pin connector distally, for attachment with a second unit, a disposable scabbard. Said second end comprises an anatomically curved disposable scabbard, proximally shaped and formed as a shroud that is sized to receive a portion of the first end. The scabbard includes proximally a corresponding male electrical pin an

adapter intended to connect with a first power unit. Such connection provides the continuity of a digital or analog image conduction system ultimately viewed externally by way of a miniature LCD screen. Said scabbard is curved having a terminal elongation, an epiglottis sweeper, for manipulating and holding the epiglottis away from covering the vocal cords to clear and expose the target anatomical structures for intubation. A plurality of functionally spaced conduits extends longitudinally through the scabbard. Advantageously, a first one of the conduits extends longitudinally through the scabbard and houses an analog or digital image conducting system with the distal end sealably housing a CMOS or digital camera system. The image signal is processed, carried proximally and electrically connecting to a first portion or power housing and ultimately to a reprocessing LCD screen with hinge/ swivel and pivoting into multiple positions for external viewing of a distal image. A second one of said conduits extends longitudinally through the scabbard and contains the proximal electrical supply to a distal and sealingly cool day light LED light which serves to illuminate the field of view. A third one of the conduits extends longitudinally through the scabbard and comprises two open ends in fluid flow communication, proximally forms an attachment to an external suction or oxygen source and opens distally to suction surrounding throat's bodily secretions or providing oxygen from an external source to the site of intubation. A fourth one of said conduits runs along an outer and dorsal surface portion of the scabbard and defines an incomplete closure conduit with at least three openings. The dorsal opening is wavy and spaced apart with thin fingers which inter digitizes its wavy pattern through the length of he incompletely formed channel. Said channel places bend tension to the endotracheal tube for a predictable exiting direction of the tube. The channel is sized to removably preload a standard endotracheal tube of a plurality of sizes.

Brief Description Of The Drawings

These and other features and advantages of the present invention will be more fully disclosed in, or rendered obvious by, the following detailed description of the preferred embodiment of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts further wherein:

Fig. 1 is a perspective view of two piece endotracheal intubation having a hinge/swivel mechanism to assume multiple angulations and positions in accordance with the present invention;

Fig. 2 is a perspective and separate view of the main assembly components with power housing assembly, hinge/swivel multiple positions LCD screen assembly and pin connectors as shown in FIG. 1. in accordance with the present invention;

Fig. 3 is a longitudinal side view and a cross-sectional view of the endotracheal intubation device shown in Fig. 1, showing an endotracheal tube conduit, an image conducting system, an electrical conduction system to distal LED cool bright light and a suction tube positioned with their respective conduits;

Fig. 4 is a dorsal view of the two piece intubation device detailing the endotracheal tube loading incomplete closure conduit showing the wavy inter digitizing pattern on the intubation device shown in Fig. 1;

Fig. 5 is a detailed distal end view of the disposable scabbard showing a CMOS camera, LED cool light suction port and loaded endotracheal tube in place as shown in fig Fig. 1;

Fig. 6 is a schematic proximal end view of a scabbard's receiving shroud containing a pin connector in the intubation device shown in Fig. 2;

Detailed Description Of Preferred Embodiment

This description of preferred embodiments is intended to be read in connection with the accompanying drawings, which are to be considered part of the entire written description of this invention. The drawing figures are not necessarily to scale and certain features of the invention may be exaggerated in scale or in somewhat schematic form in the interest of clarity and conciseness. In the description, relative terms such as "horizontal," "vertical," "up," "down," "top" and "bottom" as well as derivatives thereof (e.g., "horizontally," "downwardly," "upwardly," etc.) should be construed to refer to the orientation as then described or as shown in the drawing figure under discussion. These relative terms are for convenience of description and normally are not intended to require a particular orientation. Terms including "inwardly" versus "outwardly," "longitudinal" versus "lateral" and the like are to be interpreted relative to one another or relative to an axis of elongation, or an axis or center of rotation, as appropriate. Terms concerning attachments, coupling and the like, such as "connected" and interconnected," refer to a relationship wherein structures are secured or attached to one another either directly or indirectly through intervening structures, as well as both movable and rigid attachments or relationships, unless expressly described otherwise. The term "operatively connected" is such an attachment, coupling or connection that allows the pertinent structures to operate as intended by virtue of that relationship. In the claims, means-plus-function clauses are intended to cover the structures described, suggested or rendered obvious by the written description or drawings for performing the recited function, including not only structural equivalents but also equivalent structures.

The present invention provides a two piece endotracheal intubation device or intubator 5 that includes a hinge/swivel pivotal LCD viewing assembly mechanism 8 which enables indirect external visualization of a patient's upper airway from multiple operator positions around the patient FIG.1. The two piece field video laryngoscope includes a light weight fiber scabbard 10 and a power battery assembly 13 as shown in FIG. 2. A light weight scabbard 10 is formed from a hard polymer material formed as to generally comprise the curved anatomical shape of the throat structures. Fiber scabbard 10 includes a proximal end 12 and an anatomically curved distal end 14. Proximal end 12 defines an open end shroud 17 that is sized and shaped to accept a distal portion power assembly 13. Power assembly 13 ends with a female pin connector 16 which electrically and operatively connects with a male pin 15 connector located inside the open end shroud 17. FIG. 2. An analog or digital conduction system 20 extends throughout the length of fiber scabbard 10 and sealably ends with a CMOS or digital miniature camera 50 at the terminal face 21 of curved distal end 14 as shown in FIG.5. A second electrical conduction system 28 also extends throughout the length of fiber scabbard 10 in substantially parallel relation to analog or digital image conducting system 20 as shown in FIG. 3. A proximally operatively connection with male pin connector 16 and distally supplies current to an LED cool light 52 sealably located at the terminal face 21 of curved scabbard distal end 14. FIG. 5. A port 24 is located below shroud 17 in fluid flow communication with passageway 27. Direct external suction may be applied to port 24 and extends the length of fiber scabbard 10 and finger occlusive pressure to activation port 22 activates the vacuum source so that secretions and possibly foreign material in the throat may be transferred through a distal open end located at the terminal face 21 of curved distal end 14 and subsequently through passageway 27 serving instead of a suction catheter. FIG. 3.

An incompletely channel formed on the outer and dorsal surface of distal end 14 of fiber scabbard 10 provides an endotracheal tube receptacle. The tube receptacle 30 is sized as to snugly, but releasably accommodate a plurality of endotracheal tubes sizes 31 of the type well known in the art. Such a tube 31 may be pre positioned within the tube receptacle 30 ready for intubation at a close proximity from the target area. FIG. 5. A dorsal opening 34 is partially obstructed by a plurality of space apart, interdigitated fingers 36, which aid in snugly but releasably maintaining tube 31 with bend pressure within the receptacle 30 during insertion of fiber scabbard into a patient's mouth and throat FIG.4. Maintenance of bend pressure on said pre positioned tube 31 is desired so that the exit direction of the pre-positioned tube 31 is predictable, as shown in FIG. 4 and FIG. 5.

Power assembly 13 includes a body housing 40, a female pin electrical pin connector 15, and a hinge/swivel and multiple angular positions capable LCD screen 47. FIG.2. Power housing assembly 40 is sized and shaped to be releasably received within shroud 17 of fiber scabbard 10. FIG.2. Power housing assembly 40 encloses a long life rechargeable battery (not shown) with an on/off button 48 arranged so as to be easily accessible to an operator. Power housing assembly 40 houses a plurality of connecting ports. A first port, a battery recharging port 44 using standard alternating current (A/C) or Direct current (D/C). A second one a video output port 46 provides an extension for other media viewing or recording as shown in FIG. 2. Third one comprises an on/off switch. A fourth one comprises connecting a male pin connector 15 when operatively connected with female pin connector 16 enables powering of the entire device to include LED 52 located at the terminal face 21 of curved distal end 14 and a multi positional LCD miniature screen 47 as shown in FIG. 1.

FIG.2. Shows LCD screen assembly 47 housed in a polymer frame assembly 54 which in turn

houses a plurality of battery charge warning color coded low intensity LED lights 53. FIG. 1.

Advantageously in traumatized patients, the miniaturized color LCD screen 59 is sized and shaped to visualize the intubation process from a safe distance from possible hazardous materials. Hinged/swivel color LCD screen 47 allows for intubation from around the patient and minimal neck hyper extension thus facilitating intubation of patients with possible cervical spine or neck injury with protective neck collar in place.

Power housing assembly 40 with female electrical pin connector 16 is positioned within fiber scabbard 10 where electrically connects with the corresponding male pin connector 15 to attain a functional electrical connection within the interior of the shroud 17 once fully inserted into the shroud 17as shown in FIG.1. In this position the distal image is captured by the CMOS digital camera 50 and carried through pin connectors 15 and 16 to the Color LCD screen 59 contained within the LCD screen assembly 47.

A standard endotracheal tube 31 is then positioned into the receptacle 30 of fiber scabbard 10 by press fitting and pushing it down the receptacle 30 under the interdigitated fingers 36, so that the tube is held snugly and bend pressure but releasably in place within the preloading and incompletely formed channel 30 and within the outer portion of the fiber scabbard 10 as shown in FIG. 5.. Once this assembly is completed the intubation procedure may be started

More particularly, and unlike conventional intubation devices, the patients head and neck need not be forcefully tilted backwards at all. Unlike conventional intubation devices, minimal or no force is needed to slide the assembled two piece intubation device 5 through a small opening of the mouth and gently follow the local anatomy and quickly find the target openings. Curved distal end

14 of fiber scabbard 10 is shaped and molded to fit the general anatomy of the throat, therefore able to gently slide into a desired position by displacing the softer tissue of the tongue to reach target area, the glottis. Curved distal end 14 of scabbard 10 is then inserted through the mouth into the throat's passageway, so as to displace the soft tissue of the tongue reaching the target area, the glottis. Curved end 14 of scabbard 10 most distal end is shaped and molded to serve as an epiglottis sweeper 26 as shown in FIG.1 and FIG. 5. The epiglottis sweeper 26 is molded and shaped so as to arrive positioning itself in front of the epiglottis. This position, then allows the functionally assembled intubation device 5 for a gentle anterior sweep, towards the mouth and teeth line. This maneuver allows the sweeper to hold the epiglottis back and away from the exposed glottis opening. Once in this position, suction may be applied to port 24, so as to draw bodily secretions and fluids away from the glottis and larynx through suction passageway 27. Advantageously, the entire procedure can be visualized via Color LCD screen 59 positioning the hinge/swivel 8 LCD screen housing 47. To further advantage an analog /digital conduction system 20 provides video out port extension a video capture port 46 for possible recording and documentation of the procedure as shown in FIG. 1 and FIG2.

With the patient's larynx in view through a multiple positions the LCD screen assembly 47, pre-loaded tube 31 is maneuvered by gently pushing it down and out the channel, the tube finds its short way through the glottic opening into the tracheal cavity of the patient, all the while being observed by the person performing the intubation. Once tube 31 has been properly positioned and secured within the tracheal cavity, fiber scabbard 10 is retrieved by gently sliding said fiber scabbard 10 back and over the endotracheal tube 31 held firmly in place to reach the teeth line. Once fiber scabbard 10 has reached the teeth line, gentle wedge pressure with a finger is applied between the

endotracheal tube 31 and the partially obstructed top opening 34 as shown in FIG. 4 and interdigitated fingers 36 so as to gently force the endotracheal tube 31 out of the preloading incomplete channel 30 through the spaced apart interdigitated fingers 36. Once endotracheal tube is further secured ventilation of the patient may be begun. Power housing assembly 40 may be removed from fiber scabbard 10 by simply pulling housing 40 out from within the shroud17, electrically disconnecting the power housing assembly 13 from fiber scabbard 10. The process of intubation can be repeated as needed by simply replacing a new fiber scabbard 10 loaded with a fresh endotracheal tube 31 and reusing the power assembly 13 contained in power housing 40.

Advantages of The Invention

Numerous advantages are obtained by employing the present invention.

More specifically, an endotracheal intubation device is provided which avoids many of the aforementioned problems associated with prior art devices. The approach to intubation with gentle sliding the essentials for intubation in a small cluster to a close proximity with the glottis instead of forcing the anatomy to make way for a traditional intubating blade is preferred.

Further, bringing a cluster containing the essential for intubation to a close proximity of the target organs for intubation without trauma, forceful lifting of the tongue and jaw or the use of triggers, wheels, moving or positional grasping awkward mechanisms are avoided.

In addition, an endotracheal intubation device is provided which allows the operator to be positioned not only at the patient's head while performing an intubation (which is the conventional preferred position with very limited options), but also permits endotracheal tube placement from different positions relative to the patient's location and orientation such as intubating victims

involved in accidents and mass casualties.

Furthermore, an endotracheal intubation device is provided in which an emergency care provider may no longer need to reposition or manipulate the neck to facilitate visualization of the vocal cords, such as in the case of an automobile accident when the person is in need of respiratory assistance and there is a potential threat of neck or cervical spine injuries, which can lead to further neck, spine, and spinal cord damage, and even paralysis by repositioning of the patient's neck.

Also, an endotracheal intubation device is provided which does not require the manipulation of the neck, injured or not, to visualize the vocal cords and other anatomical structures, thus alleviating previous intubation effort related problems, such as broken or chipped teeth or neurological complications.

In addition, an endotracheal intubation device is provided, including a color LCD screen which allows the visualization of the larynx and associated structures, outside the patient's mouth and readily accessible to the operator's field of view. Further, the viewing screen can be oriented at plurality of positions about the patient's mouth and head, so as to allow the operator to intubate in tight or narrow spaces often seen in accident scenes when conventional emergency care is presently unable to do so with conventional standard equipment. This is extremely helpful when a victim is trapped inside of a vehicle where they would normally not be able to be intubated.

Furthermore, an endotracheal intubation device is provided that permits intubation from the side of a bed in a medical care facility. Previously, such intubation had to be performed from only the head of the bed, necessitating removal of the headboard of the bed to create a space between the bed and the wall, and the person maneuvering him/herself through the numerous intravenous lines and monitor equipment to be able to stand between the wall and the head of the bed, in order to place

the endotracheal tube within the patient's trachea.

In addition, an endotracheal intubation device is provided which is designed to provide disposability of the parts exposed to the patient's tissue and bodily fluids, thus minimizing or eliminating the possibility of cross contamination between patients or the possibility of exposure of one patient by another patient infected by diseases such as HIV, hepatitis, tuberculosis, among others.

In addition, an endotracheal intubation device is provided which is hand held, extremely light and portable with a long lasting own rechargeable power source and easily used in emergency medical situations involving multiple victims, shaped and ergonomically molded and curved to arrive and locate itself at the anatomical site desired for intubation.

In addition, an endotracheal intubation device is provided which is designed for visualization of the patient's anatomical structures of the throat and upper airway to minimize missed intubations, particularly those into the esophagus with possible fatal consequences.

In addition, an endotracheal intubation device is provided which permits intubation from a variety of positions of the operator relative to the patient, overcoming a common problem in accident and other emergency situations.

In addition, an endotracheal intubation device is provided which is anatomically molded and shaped so as to simply slide over the soft tissue of the throat with minimal effort or trauma to the patient during insertion

In addition, an endotracheal intubation device is provided which allows the operator to perform the insertion procedure at a distance from the patient which lessens the operator's exposure to the spread of infectious diseases and other bacterial matter by not having to hyper extend the neck

to see the vocal cords, and thereby decreasing the risk of the patient's coughing up bodily secretions into the operator's eyes and face.

In addition, an endotracheal intubation device is provided which allows for the simultaneous suctioning of bodily fluids from the throat area to eliminate the obstruction from the field of view necessary for intubation or to reversibly provide oxygen to the patient from an external pressure source.

In addition, an endotracheal intubation device is provided which requires minimal physical force on the part of the operator to expose the upper airway and larynx by introducing the functionally assembled device horizontally with respect to the lips and as the base of the tongue is reached, gently the device acquires a vertical position perpendicular to the lips anatomical and horizontal orientation, avoiding forceful and traumatic introduction into the upper airway.

In addition, an endotracheal intubation device is provided which provides an enhanced visual imaging system to assure ease of observation of anatomical structures using analog and digital technology right to the field where the emergency occurs. Further, and extension of the image carrying capacity is provided as a video output port, therefore fulfilling the need to document the intubation process.

In addition, an endotracheal intubation device which is extremely light weight, hand held , self powered with a rechargeable battery with long and continuous operation which allows for hours of operation in case of catastrophe, rescue operations and mass casualties and the military needs.

It is to be understood that the present invention is by no means limited only to the particular constraints herein disclosed and shown in the drawings, but also comprises any modifications or equivalents within the scope of the claims.